REMARKS/ARGUMENTS

The Amendments

Claims 1-2 and 9 are pending in the present case. Claims 10-17 have been canceled without prejudice. The claims have been amended to correct obvious typographic and clerical errors, and for better antecedent basis. The amendments to claim 1 specifies "*in vivo*" antioxidant activity, which is inherently supported in the as-filed claims because they specified a procedure performed *in vivo* in an animal model. The amendment to claim 3 is supported, e.g., at page 20, second full paragraph. The amendment to claim 9 is supported, *e.g.,* at page 11, second full paragraph. These amendments have been made for clarity rather than for patentability. No new matter has been added with the present Amendment.

The Telephone Interview

The Examiner is thanked for the courtesy of a telephone interview with the undersigned and Dr. Douglas C. Wallace, inventor, on October 29, 2004. During that interview, the experiments demonstrating the invention (which are forth in the specification at page 7, first full paragraph) were discussed. The rejections were also discussed, and the Examiner suggested an amendment to the preamble of claim 1, which amendment has been made. The Examiner indicated the present Response and Amendment would be entered. Should additional amendments be necessary, a further telephone call is requested.

Claim Rejections:

The pending claims are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Applicants respectfully traverse this rejection and provide the following comments.

The present invention is a method for identifying a compound as an *in vivo* antioxidant by employing homozygous transgenic mice in which the genes encoding manganese superoxide dismutase (MnSOD) have been inactivated. The method as set forth in claim 1 involves administering a test compound to homozygous transgenic mice and comparing the lifespan of such mice with that of similar mice not treated with the compound. If the mice treated with the compound have longer lifespans than those of the untreated mice, the compound is identified as an *in vivo* antioxidant.

The invention set forth in claims 1, 2 and 9 is based on the actual experimental results disclosed in the specification at page 7, first full paragraph, *i.e.*, the inventors herein discovered that when the homozygous transgenic mice (Sod2CJE(-/-)) were treated with MnTBAP, a compound whose *in vitro* antioxidant activity was known, but whose *in vivo* antioxidant activity was not previously known, the treated mice survived significantly longer than those not treated with this antioxidant.

The Office Action states:

> A number of features are critical or essential to the practice of the invention, but not included in the claims . . . .. It would appear, but is unclear, that the administration of KNOWN antioxidant compounds prior to the administration of test antioxidant compounds is essential to the claimed invention. However, no such multiple administration is shown and therefore no compounds are found which have antioxidant activity, which is what is presently claimed.

As described above, claim 1 specifies an assay for identifying compounds with *in vivo* antioxidant activity. Since the mice used in the assay lack superoxide dismutase and therefore have no ability to detoxify oxygen radicals, these test mice typically die by the time they are eleven days old, on average (see page 6, last partial paragraph). If they are treated with a compound that acts as an effective antioxidant, such as MnTBAP, they live longer than untreated mice. There is no need to administer a known antioxidant in this assay.

Claims 10-17 did specify the administration of a known antioxidant as part of an assay for comparison purposes, but these claims to more complex assays have been canceled without prejudice in order to avoid confusion.

The Office Action further states: "No screening of any compounds is shown in the specification as originally filed." In fact, however, the specification demonstrates the screening method using MnTBAP. The screening method is thus fully enabled and shown to be operational. Additional compounds may be screened following the procedure described with respect to this compound by anyone skilled in the art without undue experimentation.

In the recently-decided case, *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CAFC, 2004), the court held a patent claiming compounds identified by a screening method to be invalid because no specific compounds were disclosed in the specification. However, the validity of the plaintiff's previously-issued patent (Patent No. 5,837,479) claiming the screening method itself was not in question, and remains valid even though no compounds identified in the screening method were disclosed in the specification.

The present situation is analogous except for the fact that the present specification does, in fact, disclose a compound identified by the screening method as an *in vivo* antioxidant, namely MnTBAP. There is no requirement that an application for a patent on a screening method disclose particular compounds that are to be run through the screen in order to validly claim the screening method itself.

Conclusion:

Based on the foregoing amendments and arguments, this case is deemed to be in condition for allowance and passage to issuance is respectfully requested.

If there are further issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This Amendment is accompanied by a Petition for Extension of Time and the required fees. If the amount submitted is incorrect, however, please refund or charge any fees necessary to Deposit Account No. 07-1969.

This Amendment is also accompanied by a Notice of Appeal and the required fee.

Respectfully submitted,

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